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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Christina Khoo, *et al.*
Application No:	10/729,450
Filed:	December 5, 2003
Group Art Unit:	1651
Confirmation No:	1031
Examiner:	Allison M. Ford
Date:	June 23, 2006
Attorney Reference:	7129-00
Title:	COMPOSITION AND METHOD

TRANSMITTAL LETTER

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

Dear Sir:

Transmitted herewith is an Appeal Brief submitted pursuant to 37 C.F.R. §41.37. Please charge the fee for filing a brief in support of an appeal under 37 C.F.R. §41.20(b)(2) to Deposit Account No. 502957.

Please charge any shortage in fees or credit any excess fees during the entire pendency of this Application to Deposit Account No. 502957.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being transmitted by facsimile to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on June 23, 2006 at facsimile number 571-273-8300.

Wendell Ray Guffey

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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APPEAL BRIEF PURSUANT TO 37 C.F.R. §41.37

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P.O. Box 1450
Alexandria, VA 22313

Dear Sir:

Appellants hereby appeal to the Board of Patent Appeals and Interferences from the final rejection of claims 1-15, 17 and 19 in the application.

Appellants filed a timely Notice of Appeal on April 24, 2006 under 37 C.F.R. §41.31(a) from the action of the Examiner in finally rejecting claims 1-15, 17 and 19 in the application.

I. Real Party in Interest

The real party in interest is Hill's Pet Nutrition, Inc., a Delaware corporation having a place of business at 400 SW 8th Avenue, Topeka KS 66603, the assignee of record and a wholly-owned subsidiary of Colgate-Palmolive Company, a Delaware corporation having a place of business at 300 Park Avenue, New York, NY 10022.

II. Related Appeals and Interferences

Appellant knows of no other appeals or interferences that will directly affect or be directly affected by or that have a bearing on the Board's decision in the pending appeal.

III. Status of Claims

Claims 1-15, 17 and 19 are pending in the application and are the subject of this appeal.

Claims 1-15, 17, and 19 are rejected under 35 U.S.C. 103(a) as obvious over Shields, Jr. *et al.* (U.S. Patent No. 6,156,355) in view of Wadsworth *et al.* (U.S. Patent No. 6,737,089) and Klimberg *et al.* (Arch. Surg., 1990).

IV. Status of Amendments

No amendment was filed subsequent to final rejection. Pending claims 1-15, 17 and 19 correspond to those submitted on January 5, 2006 in response to the non-final Office action mailed October 18, 2005. A copy of the pending claims is included in Appendix A hereto, in accordance with 37 C.F.R. §41.37(c)(1)(viii).

V. Summary of Claimed Subject Matter

The present invention generally provides (1) a composition that can be used by a mammal having GI tract inflammation comprising at least about 0.1% by weight glutamine, at least about 0.5% by weight fermentable fiber(s), at least about 0.1% by weight antioxidant(s), and at least about 0.1% by weight omega-3 fatty acid(s); (2) a method for managing diarrhea in a mammal having GI tract inflammation; and (3) a method for managing diarrhea in a non-canine mammal by orally administering such composition to the mammal.

The invention is claimed in independent claims 1, 14, and 19. Support for claim 1 is given in the Specification at page 1, lines 19 through 22 and page 2, line 8 through page 3, line 8. Support for claim 14 is given in the Specification at page 1, lines 19 through 22 and in Example 1. Support for claim 19 is given in the Specification at page 1, lines 23 through 25 and in Example 1.

VI. Grounds of Rejection to be Reviewed on Appeal

Is the invention as claimed in pending claims 1-15, 17, and 19 obvious under 35 U.S.C. 103(a) over Shields, Jr. et al. (U.S. Patent No. 6,156,355) in view of Wadsworth et al. (U.S. Patent No. 6,737,089) and Klimberg et al. (Arch. Surg., 1990)?

VII. Argument

A. Rejection under 35 U.S.C. § 103(a)

1. Applicable Law

The Supreme Court in *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 U.S.P.Q. 459, 467 (1966) set forth the test for determining obviousness under 35 U.S.C. §103(a). Determining obviousness requires four kinds of factual inquiries:

(1) the scope and content of the prior art;
(2) the differences between the prior art and the claimed invention;
(3) the level of ordinary skill in the field of the invention; and

(4) any objective indicia of success such as commercial success, long felt need, and copying.

See also, Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH, 139 F.3d 877, 881, 45 U.S.P.Q.2d 1977 (Fed. Cir. 1998).

Further, the initial burden of establishing a basis for denying patentability to a claimed invention rests upon the Examiner. *In re Fine*, 5 U.S.P.Q.2d 1596 (C.A.F.C. 1988). To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP 2143.

In addition, it is well established that there must be some teaching in the references that would provide a motivation or logical reason to a person of ordinary skill in the art to combine the teachings of the references to establish a *prima facie* case of obviousness. See, *W.L. Gore and Associates v. Garlock*, 220 U.S.P.Q. 303 (Fed. Cir. 1983) and *A.S.C. Hospital Systems, Inc., v. Montefiore Hospital*, 221 U.S.P.Q. 929 (Fed. Cir. 1984). When obviousness is based upon a combination of prior art references, there must be a showing of a suggestion or motivation to combine the teachings of those references. *See Gambro Lundia AB v. Baxter Corp.*, 110 F.3d 1573, 1579, 42 U.S.P.Q.2d 1378 (Fed. Cir. 1997) (The absence of such a suggestion to combine prior art references is dispositive in an obviousness determination). *See also B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1582-83, 37 U.S.P.Q.2d 1314, 1318 (Fed. Cir. 1996); *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598-99 (Fed. Cir. 1988). Further, such a combination cannot be based upon "hindsight" that results from the use of applicant's own invention to justify the combination. *See W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983) ("To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher"). Case law makes it clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the

teaching or motivation to combine prior art references. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998) (a teaching or suggestion or motivation to combine references is as an essential evidentiary component of an obviousness holding).

A prior art reference may be considered to teach away when "a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *See In re Gurley*, 27 F.3d 551, 553, 31 U.S.P.Q.2d 1130, 1131 (Fed. Cir. 1994).

2. Claim Rejections

Claims 1-15, 17, and 19 stand rejected under 35 U.S.C. 103(a) as obvious over Shields, Jr. *et al.* in view of Wadsworth *et al.* and Klimberg *et al.* Basically, the question in the present case is whether a fair reading of these three (3) separate and demonstratively different references as a whole would suggest combining the references to achieve the present invention to one of ordinary skill in the art at the time of the invention.

A. The Scope and Content of the Prior Art

Shields, the principal reference, discusses breed-specific dog food formulations comprising chicken meat as the major ingredient. The reference discusses a single formulation in the form of a "herding diet" that includes fiber, omega-3 fatty acids, and antioxidants along with microbial cultures, bromelain (a pineapple extract) and glutamine for breeds that suffer from gastrointestinal immune deficiency. However, nothing in the reference teaches or suggests ameliorating diarrhea in a mammal having GI tract inflammation. Further, as acknowledged by the Examiner at page 4 of the first Office action, the reference is devoid of any teaching regarding specific amounts of glutamine or omega-3 fatty acids.

Wadsworth and Klimberg, the secondary references, teach the inclusion of particular amounts of glutamine and antioxidants in compositions for improving gastrointestinal health.

Wadsworth discuss animal food formulations containing *Morinda Citrifolia* extract as providing improved digestive system support. Although glutamine and antioxidants are listed as components of reported formulations, the reference fails to teach or suggest any importance of including any particular amount of glutamine or antioxidants in a composition for improving gastrointestinal health.

Klimberg discusses the administration of glutamine to protect intestinal mucosa of rats from radiation-induced ulceration. Although glutamine is discussed for its healing effects in patients undergoing whole abdominal radiation, nothing in the reference teaches or suggests alleviating diarrhea in a patient suffering from GI tract inflammation or whether glutamine would provide healing effects in a formulation comprising other components such as fermentable fiber, antioxidants or omega-3 fatty acids. Further, there is nothing to suggest that patients suffering from radiation damage and patients suffering from GI tract inflammation would respond similarly to agents used for treating the conditions, particularly glutamine.

B. The Differences between the Prior Art and the Claimed Invention

(1) Claims 1-13

In contrast to the cited references, claims 1-13 of the present application are directed to methods and compositions useful in ameliorating diarrhea caused by GI tract inflammation in a mammal. In particular, independent claim 1 is directed to a composition suitable for oral ingestion by a mammal having GI tract inflammation wherein the composition comprises at least about 0.1% by weight glutamine, at least about 0.5% by weight fermentable fiber(s), at least about 0.1% by weight antioxidant(s), and at least about 0.1% by weight omega-3 fatty acid(s). The present invention as defined in claim 1 differs from Shields and the secondary references in that it claims a combination of specific ingredients and specific amounts of those ingredients that can be used to combat inflammation and diarrhea. Shields teaches using the herding diet for breeds that suffer from gastrointestinal immune deficiency; the present invention is directed to ameliorating diarrhea caused by GI tract inflammation (not immune deficiency). Wadsworth discloses food formulations that contain antioxidants and glutamine as a minor component but does not provide information as to amounts or effects; the present invention uses such compounds in specific given amounts for a specific purpose, i.e., ameliorating diarrhea caused by GI tract inflammation. Klimberg discusses the administration of glutamine to protect intestinal mucosa of rats from radiation-induced ulceration; the present invention claims a combination of glutamine and other critical ingredients to ameliorate diarrhea caused by GI tract inflammation. The claimed invention does not seek to protect the animal from radiation or other agents but seeks to ameliorate the effects of inflammation, particularly diarrhea that results from such inflammation.

Further, there is nothing in the cited references to motivate a skilled artisan to combine the references to produce the present invention or to lead such artisan to believe that a combination of the references would give a reasonable expectation of success in developing the present invention, particularly since the cited references do not provide or suggest useful amounts of the ingredients and are preventative rather than ameliorating. Given this limitation in the cited art, the development of the present invention can only be achieved through the inappropriate use of hindsight and the teaching in applicant's disclosure.

Claims 2-13, which depend directly or indirectly from claim 1, contain all the limitations of claim 1 and are accordingly novel over the cited references for at least the same reasons as given for claim 1. Further, each dependent claim contain specific range limitations for the claimed ingredients. Certainly, none of those range limitations are taught in the cited references nor is there any motivation or suggestion that would make a skilled artisan likely to be reasonably successful in determining the ranges.

(2) Claim 15

Dependent claim 15, dependent on claim 1, is limited to "non-canine" animals. Shields discloses breed-specific dog food formulations that are for administration to specific breeds of canines. However, there is nothing in the scope and content of Shields, alone or in combination with Wadsworth and Klimberg, that teaches or motivates a skilled artisan to conclude that the formulations would be effective in animals other than canines.

(3) Claim 14 and 17

Independent claim 14 is directed to a method for managing diarrhea in a mammal having GI tract inflammation. The method comprises orally administering to the mammal the composition defined in claim 1. Claim 14 differs from the cited references in that it is specifically directed to managing diarrhea. Nothing in Shields or the secondary references disclose anything relating to diarrhea. Further, there is nothing in the cited references that would motivate a skilled artisan to combine the references to achieve the invention claimed in claim 14. In fact, the cited references cannot be combined to achieve the claimed invention so there can be no reasonable expectation of success if the references are combined.

Claim 17, which depend directly from claim 14, contain all the limitations of claim 14 and are accordingly novel over the cited references for at least the same reasons as given for claim 14.

(3) Claim 19

Independent claim 19 is directed to a method for managing diarrhea in a non-canine mammal. As stated above, Shields and the secondary references do not teach, suggest, or motivate an invention relating to non-canine animals. In fact, Shields is directed exclusively to canine animals. Further, there is nothing in the cited references to motivate one to combine such references to achieve the present claimed invention.

C. The Obviousness Determination

Basically, the Examiner failed to appreciate the differences between the claimed invention and the scope and content of the prior art and has apparently used hindsight reconstruction to reach the decision that the present claims are obvious over a combination of the cited references. Thus, the Examiner has failed to meet the burden of proof and establish a *prima facie* case of obviousness. Further, even if a *prima facie* case of obviousness arguably could be established, applicants have successfully rebutted such case by distinguishing the present invention over the cited art. The invention as claimed, therefore, is not obvious over a combination of the cited references.

C. Conclusion

Appellant submits that the present invention is not obvious over the combination of Shields, Wadsworth, or Klimberg. All claims are believed to be allowable. Reversal of the rejection of claims 1-15, 17, and 19 under 35 U.S.C. §103(a) is respectfully requested.

VIII. Claims Appendix

The Board's attention is respectfully drawn to Appendix A hereto.

IX. Evidence Appendix

No evidence is entered in this Appeal Brief.

X. Related Proceedings Appendix

No related proceedings are identified herein.

Respectfully submitted,

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Appendix A

Claims Pending on Appeal

1. (previously presented) A composition suitable for oral ingestion by a mammal having GI tract inflammation comprising at least about 0.1% by weight glutamine, at least about 0.5% by weight fermentable fiber(s), at least about 0.1% by weight antioxidant(s), and at least about 0.1% by weight omega-3 fatty acid(s).

2. (original) The composition in accordance with claim 1 wherein the mammal is a dog or a cat.

3. (original) The composition in accordance with claim 2 wherein the composition is administered in the diet of the dog or cat.

4. (previously presented) The composition in accordance with claim 3 wherein glutamine comprises from about 0.1 to about 5 percent by weight of the diet.

5. (previously presented) The composition in accordance with claim 3 wherein the fermentable fiber(s) comprises from about 0.5 to about 20 percent by weight of the diet.

6. (previously presented) The composition in accordance with claim 3 wherein the antioxidant(s) comprises from about 0.1 to about 3 percent by weight of the diet.

7. (previously presented) The composition in accordance with claim 3 wherein the omega-3 fatty acid(s) comprises from about 0.1 to about 3 percent by weight of the diet.

8. (previously presented) The composition in accordance with claim 4 wherein the fermentable fiber(s) comprises from about 0.5 to about 20 percent by weight of the diet.

9. (previously presented) The composition in accordance with claim 4 wherein the antioxidant(s) comprises from about 0.1 to about 3 percent by weight of the diet.

10. (previously presented) The composition in accordance with claim 4 wherein the omega-3 fatty acids(s) comprises from about 0.1 to about 3 percent by weight of the diet.

11. (previously presented) The composition in accordance with claim 8 wherein the antioxidant(s) comprises from about 0.1 to about 3 percent by weight of the diet.

12. (previously presented) The composition in accordance with claim 8 wherein the omega-3 fatty acid(s) comprises from about 0.1 to about 3 percent by weight of the diet.

13. (previously presented) The composition in accordance with claim 11 wherein the omega-3 fatty acid(s) comprises from about 0.1 to about 3 percent by weight of the diet.

14. (previously presented) A method for managing diarrhea in a mammal having GI tract inflammation comprising orally administering to the mammal a composition comprising at least about 0.1% by weight glutamine, at least about 0.5% by weight

fermentable fiber(s), at least about 0.1% by weight antioxidant(s), and at least about 0.1% by weight omega-3 fatty acid(s).

15. (previously presented) The composition in accordance with claim 1 wherein the mammal is a non-canine mammal.

16. (canceled).

17. (previously presented) The method of claim 14 wherein the mammal is a non-canine mammal.

18. (canceled).

19. (previously presented) A method for managing diarrhea in a non-canine mammal comprising orally administering to the mammal a composition comprising:

from about 0.1% to about 5% by weight glutamine;

from about 0.5% to about 20% by weight fermentable fiber(s);

from about 0.1% to about 3% by weight antioxidant(s); and

from about 0.1% to about 3% by weight omega-3 fatty acid(s).

20. (canceled).